REMARKS

Applicant appreciates the thorough review and analysis by the Examiner, Applicant respectfully requests reconsideration based upon the amendments and the remarks contained herein. The Examiner rejected claims 33 and 49 as being unpatentable under the provisions of 35 U.S.C. §112. Applicant believes that the amendments to such claims alleviate such rejections. Applicant no longer refers to "spiral-flow inducing properties" but now includes features that create spiral or helical flow, which is discussed throughout the specification of the Application. Applicant has also further defined the relationship between the rigid support rod and the sleeve such that there is clear understanding of how the sleeve can be contractible relative to the rod. Applicant respectfully requests the Examiner remove these rejections.

The Examiner rejected claims 33-37 and 47-49 as unpatentable under the provisions of 35 U.S.C. § 102(b) for being anticipated by U.S. Patent No. 5,989,230, issued to James J. Frassica (hereinafter "the Frassica patent" or "Frassica"). Frassica must disclose each and every claim limitation in order to anticipate Applicant's claims. However, Frassica does not teach or disclose, for example, "an intravascular stent." Frassica, on the other hand, teaches catheters, stents, other devices to be used within the genitourinary and gastrointestinal passages and organs. *See* the Frassica patent (Abstract). With reference to the specific stent embodiment relied upon by the Examiner, Frassica teaches that the stent of Figures 16-18 is a urethral stent, with alternative embodiments being conducive for use in the prostate or sphincter. *See* the Frassica patent (Col. 19: ll. 17-20, and ll. 36-41). Moreover, in the summary of the invention section of the Frassica patent, Frassica explains that the Frassica stent is specifically used for allowing urine flow through the urethra from the bladder and for allowing examination of the bladder. *See* the Frassica patent (Col. 9: ll. 31-47). Because Frassica fails to disclose "an intravascular stent,"

Applicant respectfully submits that claims 33-37, 47-49, and 53-54 are allowable, and respectfully requests reconsideration of the Examiner's rejection based upon the Frassica patent.

Claim 33 also includes the limitation that the stent has "a mesh member, the mesh member having an internal helical formation to induce spiral-flow therethrough." The Examiner alleged that Frassica disclosed a stent that was an expansible mesh member with respect to previously presented claim 34, and that the outer thread 303 of Frassica would induce spiral flow. Applicant respectfully submits that Frassica does not anticipate claim 33.

First, the urethral stent shown in Figures 16-18 was a tube made of polyurethane, and is not a mesh member. Frassica specifically states that prior mesh stents had openings that allow the tissue to grow through the wall, thereby making removal difficult and causing encrustation that reduces urine flow. *See* the Frassica patent (Col. 5: ll. 40-47). This was presented as a problem associated with stents prior to the Frassica stent. Accordingly, the Frassica stent is a tubular polyurethane that is not mesh, with a helical outer thread to help advance and retain the stent within the urethra while also not being susceptible to being incorporated into the tissue. *See* the Frassica patent (Col. 9: ll. 41-44). Thus, the Frassica patent does not teach a stent as shown in Figures 16-18 (with outer thread 303) that is made of a mesh material, rather Frassica specifically teaches away from uses mesh material.

Moreover, thread 303 is positioned along the outer surface of the stent 301. Therefore, thread 303 is not "an internal helical formation" and cannot induce spiral-flow through the stent.

Furthermore, Frassica fails to disclose that the coiled sidewall reinforcement member 310 induces spiral flow through the stent 301. Rather the purpose of the member 310 is for reinforcing the outer walls of stent 301 to prevent it from collapsing due to the pressure from the organ or passageway the stent 301 is positioned within. *See* the Frassica patent (Col. 9: ll. 35-37;

Col. 19: ll. 34-36, 39-41). Coiled sidewall reinforcement member 310 also would not induce spiral flow because it is too tightly wound. Rather, the urine flows over each successive turn of coiled member 310 and becomes turbulent flow rather than helical or spiral flow. Because the Frassica patent also fails to show "a mesh member, the mesh member having an internal helical formation to induce spiral-flow therethrough," Applicant respectfully submits that claims 33-37 and 49 are allowable and requests reconsideration of the Examiner's rejection.

With respect to claims 36 and 37, the Examiner alleged that Frassica discloses that coiled member 310 induces spiral flow and is adjustable (claim 36), and an adjustable helix angle (claim 37). Applicant has already discussed herein that coiled member 310 fails to induce spiral flow, but Applicant further respectfully disagrees that Frassica discloses coiled member 310 as being adjustable. Rather the passage relied refers to adjusting the "thread" so that it is "tapered to a lesser height or no height, to provide 'waist' for gripping by a muscular zone such as the prostate or sphincter." *See* the Frassica patent (Col. 19: ll. 34-36). The "thread" referred to in the cited section is the Frassica thread 303 that extends around the exterior of the Frassica stent 301 and is engaged by the walls of the urethra, or the muscles of the prostate and sphincter. There is no teaching that the coiled sidewall reinforcement member 310 is adjustable. Therefore, Applicant respectfully submits that, for this additional reason, claims 36-37 are allowable and requests reconsideration of the Examiner's rejection.

In addition to depending from allowable claim 33, Applicant respectfully submits that claim 49 is also patentable because Frassica fails to show several of the required elements, specifically a "flexible sleeve surrounding the support rod" and a "helical vane mounted to the sleeve." The Examiner alleged that the tube of the Frassica stent 301 was the flexible sleeve, the outer thread 303 was a rigid rod, and the coiled sidewall reinforcement member 310 was the

helical vane. Applicant's claim 49 now defines the relationship of the sleeve to the support rod more clearly such that the sleeve surrounds the rigid support rod. In Frassica, the previously-alleged support rod extends around the sleeve. Therefore, Applicant respectfully submits that the Frassica fails to anticipate claim 49, and Applicant respectfully submits that, for this additional reason, claims 47 are allowable and requests reconsideration of the Examiner's rejection

Claim 47 also includes that the stent is "an intravascular stent" that includes "an expansible tubular mesh member" and a "vane stationarilly attached to an interior [of the mesh member] and extending helically to induce spiral flow of blood." As discussed above, the Frassica patent teaches away from using mesh material, and therefore the Frassica stent 301 is a polyurethane tube. Frassica does not disclose the prior art stents having anything to induce spiral flow. Moreover, as discussed above, Frassica does not disclose a vane in the Frassica stent 301 that is attached to the interior thereof for inducing spiral flow because coiled member 301 is wound so tightly that it would merely cause turbulent flow. Furthermore, Applicant has amended claim 47 such that the "adapted to" clause is removed, and therefore Applicant is positively claimed that the mesh member is sized to be inserted and retained within a vein. Therefore, the Frassica patent also fails to anticipate claim 47 because it fails to show several of the same elements of claim 33 as well as additional elements in claim 47.[1] Accordingly, Applicant respectfully submits that, for this additional reason, claims 47-48 are allowable and requests reconsideration of the Examiner's rejection.

With respect to claim 48, the Examiner alleges that "metallic mesh necessarily comprises a plurality of wires that extend helically and cross each other to form junctions." Applicant respectfully disagrees. One set of wires of a metallic mesh can extend longitudinally and parallel

[1] Support for such amendment is found in paragraph [0022] of the Application as well as in claim 34.

with an axis of the stent, with the crossing set of wires extending circumferentially to create junctions. The two sets of wires of a metallic mesh do not "necessarily" have to "extend helically and cross each other to form junctions," as alleged by the Examiner. Therefore, because the element of claim 48 is not shown in the Frassica patent, Applicant respectfully submits that claim 48 is allowable and requests reconsideration of the Examiner's rejection.

New claims 53-54 depend from claim 37, which also depends indirectly from claim 33. Therefore, Applicant respectfully submits that claims 53-54 are allowable. Claims 53-54 further define the acceptable range for the helix angle and the preferred helix angle respectively. Support for such claims is in paragraph [0013] of the Application. As stated in paragraph [0013], helical formations with a helical angle greater than 50 degrees will unduly restrict flow, and those under 5 degrees will have little effect on the flow. This makes sense because of the helical angle is less than 5 degrees, the helix is less than 5 degrees off of the extending longitudinally, which would cause very little swirling of the fluid (specifically blood) passing therethrough. In contrast, when the helix extends at an angle greater than 50 degrees from longitude, the helix becomes more tightly wound, like the Frassica coiled sidewall reinforcement member 310, and would thereby cause turbulence and restrict flow.

CONCLUSION

Applicant respectfully submits that claims 33-37, 47-49, and 53-54 are all in condition for allowance. Reconsideration of the application and allowance of all claims are respectfully requested, and Applicant respectfully requests the issuance of a Notice of Allowance.

Respectfully submitted,

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